UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/594,349 | 05/29/2007 | Masato Miyake | 690121.410USPC | 5580 |

500 7590 06/21/2010

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 5400
SEATTLE, WA 98104

| EXAMINER | |
|---|---|
| EPPS -SMITH, JANET L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1633 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 06/21/2010 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/594,349 | MIYAKE ET AL. | |
| | Examiner | Art Unit | |
| | Janet L. Epps-Smith | 1633 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *06 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *13-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 October 2007* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of Group I, claims 1-12, and substance D in the reply filed on 04/06/2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Substance D is drawn to the following: A protein molecule comprising SEQ ID NO: 11, or at least amino acids 21 to 241 of SEQ ID NO: 11 constituting an Fn1 domain, or a variant or fragment thereof; having at least one mutation selected from the group consisting of at least one amino acid substitution, addition, and deletion, and having a biological activity; or homolog; or a polypeptide having 70% identity to said protein.

2. Claims 13-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04-06-2010.

### *Drawings*

3. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the details of Figures 1, 24, and 35 cannot be properly discerned. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepare new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 5-6 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 5 recites the limitation "the Fn1 domain" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 6 recites the limitation "the protein molecule having the Fn1 domain" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 8 recites the limitation "wherein the gene introduction reagent..." in claim 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4, 7-8, and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanenberg et al.

10. Instant claims 1-3 are drawn to a composition for increasing the efficiency of introducing a target substance into a cell, comprising: an actin acting substance, wherein the actin acting substance may be an extracellular matrix protein or a variant or fragment thereof, and further wherein said substance is fibronectin, laminin, and vitronectin, or a variant or fragment thereof. Claim 4 recites wherein the actin acting

substance is a protein molecule comprising SEQ ID NO: 11, or at least amino acids 21 to 241 of SEQ ID NO: 11 constituting an FnI domain, or a variant or fragment thereof; having at least one mutation selected from the group consisting of at least one amino acid substitution, addition, and deletion, and having a biological activity; or homolog; or a polypeptide having 70% identity to said protein.

11. Hanenberg et al. describe the use of compositions comprising fibronectin to increase the efficiency of retroviral gene transfer in to cells. In one embodiment, Hanenberg et al. recombinant fibronectin fragments CH-296 or 271 was used. CH-296 was dissolved in phosphate buffered saline (see page 2198). CH-296 or 271 was used for coating plates. The primary hematopoietic cells were transfected on the coated plates, see Figure 2. Hanenberg et al. also performed transduction experiments using polycations to improve gene transfer efficiency. However, it was concluded that the presence of the polycations did not improve gene transfer efficiency above that observed for the presence of fibronectin fragments (see page 2201).

12. Regarding claim 4, it is clear that Hanenberg et al. uses two fragments of fibronectin to improve gene transfer efficiency. Absent evidence to the contrary, the fibronectin fragments of CH-296 and CH-271 used in the experiments of Hanenberg et al. exhibit biological activity, and further read on the limitations of claim 4 to the extent that these fragments comprise *at least one* substitution, addition, or deletion to the sequence of SEQ ID NO: 11, which encodes Bovine Fibronectin Protein.

13. Claims 1-4 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Rabbani et al.

14. Rabbani et al., see ¶ [0184], teach that fibronectin can also be used for the covalent attachment of a nucleic acid component for delivery of nucleic acid to cells. For example, fibronectin, a fibronectin fragment or fibronectin containing compounds can be attached to either a polynucleotide or to a virus vector."

15. Rabbani et al. also discloses the following: ¶ [0044] "[A]lso provided is a multimeric composition comprising more than one component attached to a charged polymer. In this composition, the charged polymer is selected from a polycationic polymer, a polyionic polymer, a polynucleotide, a modified polynucleotide and a polynucleotide analog, or any combination of the foregoing elements.

***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanenberg et al. or Rabbani et al. in view of Skorstengaard et al. and Kitazato et al.

18. The teachings of Hanenberg et al. and Rabbani et al. as set forth above are incorporated here. These references do not teach wherein the fibronectin compositions for increasing efficiency of introducing a target substance into a cell, comprises an Fn1

domain of amino acids 21 to 577 of SEQ ID NO: 11, further comprises a particle or wherein the particle comprises gold colloid.

19. Skorstengaard et al. describes the complete sequence of bovine plasma fibronectin, this sequence comprises at least amino acids 21 to 577 of SEQ ID NO: 11.

20. Kitazato et al. describe the labeling of gene therapy vectors with gold colloid.

21. It would have been obvious, at the time of the invention, to the ordinary skilled artisan to modify the teachings of Hanenberg et al. or Rabbani et al. with the teachings of Skorstengaard et al. and Kitazato et al. in the design of the instant invention.

22. It would have been obvious to substitute the fibronectin used in the compositions of Hanenberg et al. or Rabbani et al. with the fibronectin of Skorstengaard et al. One of ordinary skill in the art would have been motivated to make this modification because as per MPEP § 2144.06 [R-6], it is *prima facie* obvious to substitute art recognized equivalents for the same purpose.

23. Secondly it would have been obvious to the ordinary skilled artisan to modify the gene delivery particles described in the primary references with the gold colloid modification of Kitazato et al. since the prior art teaches that this class of modification is well suited for gene delivery vehicles and is useful for visualization of the modified particles.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633